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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,477	04/08/2004	Theresa M. Siler-Khodr	P-7345.2(CIP)6	8636

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,477	SILER-KHODR, THERESA M.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim 1 recites an amino acid sequence which is not identified by a SEQ ID NO: and furthermore does not appear to correspond to a as a sequence in the computer-readable form of the sequence listing. 37 CFR 1.821(a)(2)(c-d) states that each sequence disclosed must appear separately in the Sequence Listing and in the text of the description **and the claims** whenever referred to.

Applicant is advised that failure to respond to both the requirement to fully comply with the sequence rules and the restriction requirement below may result in abandonment of the application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 8, drawn to chicken II GnRH analogs and pharmaceutical compositions, classified in class 514, subclass 12, for example.

II. Claims 9 – 11, drawn to antibodies that bind to chicken II GnRH, classified in class 424, subclass 139.1, for example.

III. Claim 12, drawn to a method of determining whether a sample contains chicken II GnRH, classified in class 435, subclass 7.1, for example.

IV. Claims 13 – 15, drawn to antibodies that bind to chicken GnRH receptor, classified in class 424, subclass 139.1, for example.

V. Claims 16, drawn to a method of determining whether a sample contains chicken II GnRH receptors, classified in class 435, subclass 7.1, for example.

VI. Claims 17 – 19, drawn to a method of determining if a sample contains nucleic acid encoding chicken II GnRH, classified in class 435, subclass 6.

VII. Claims 20 – 22, drawn to a method of determining if a sample contains nucleic acid encoding chicken II GnRH receptor, classified in class 435, subclass 6.

VIII. Claims 23 and 40, drawn to methods of regulating translation of SEQ ID NO:8 or secretion of SEQ ID NO:6 comprising introducing oligonucleotides complementary to SEQ ID NO:8 into cells, classified in class 514, subclass 44.

IX. Claims 24, 38 – 39 and 41, drawn to methods of regulating translation of SEQ ID NO:1 or transcription or translation of the nucleic acid for the receptor that binds SEQ ID NO:6, or secretion of SEQ ID NO:6 comprising introducing oligonucleotides complementary to SEQ ID NO:1 into cells, classified in class 514, subclass 44.

X. Claim 25, drawn to methods of regulating translation of mRNA complementary to SEQ ID NO:8 comprising introducing oligonucleotides comprsing at least 10 consecutive nucleotides of SEQ ID NO:8 into cells, classified in class 514, subclass 44.

XI. Claim 26, drawn to methods of regulating translation of mRNA complementary to SEQ ID NO:1 comprising introducing oligonucleotides comprsing at least 10 consecutive nucleotides of SEQ ID NO:1 into cells, classified in class 514, subclass 44.

XII. Claims 27, 28, 33 – 35, 42 – 43, 46 – 47, drawn to a method of regulating transcription of SEQ ID NO:6 or 8, or translation of the receptor for SEQ ID NO:6, or function of the receptor for SEQ ID NO:6, or secretion of SEQ ID NO:6, or secretion of the receptor for SEQ ID NO:6, comprising administering the polypeptide of SEQ ID NO:6 to a cell, classified in class 514, subclass 12.

XIII. Claim 29, drawn to a method of regulating translation of SEQ ID NO:6 comprising introducing an olgionucleotide comprising at least 10 consecutive nucleotides complementary to SEQ ID NO:1 into a cell, classified in class 514, subclass 44.

XIV. Claim 30, drawn to a method of regulating translation of SEQ ID NO:6 comprising introducing an olgionucleotide comprising at least 10 consecutive nucleotides of SEQ ID NO:1 into a cell, classified in class 514, subclass 44.

XV. Claim 31-32, 44 – 45, drawn to a method of regulating transcription or secretion of chicken II GnRH receptor comprising administering a nucleic acid complementary to the nucleic acid which encodes a receptor for SEQ ID NO:6, classified in class 514, subclass 44.

XVI. Claim 36 – 37, drawn to a method of regulating transcription or translation of the complement of the DNA of the receptor for SEQ ID NO:6, comprising administering an olgionucleotide encoding the receptor for SEQ ID NO:6, classified in class 514, subclass 44.

XVII. Claims 48 – 50, drawn to a method of regulating transcription of SEQ ID NO:8 or translation of SEQ ID NO:6 or regulating the secretion of SEQ ID NO:6 comprising administering SEQ ID NO:6 to a cell and triggering a biological mechanism within the cell, classified in class 514, subclass 12.

XVIII. Claims 51 – 52, drawn to purified polypeptides and pharmaceutical preparations comprising same, classified in class 514, subclass 12.

XIX. Claim 53, drawn to methods of treating patients or animals comprising administering a polypeptide with SEQ ID NO:6, classified in class 514, subclass 12.

XX. Claim 54, drawn to methods of treating patients or animals comprising administering a receptor to polypeptide SEQ ID NO:6, classified in class 514, subclass 12.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and XVII are independent and distinct from Inventions II and IV because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptides of Group I and XVII and the antibodies of Groups II and IV are patentably distinct for the following reasons: while the inventions in all groups are polypeptides, in this instance, the polypeptides of Groups I and XVII are single chain molecules, whereas the antiboides of Groups II and IV antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of Groups I and XVII and the antibodies of Group II and IV are structurally distinct molecules; any relationship between a polypeptide of Group I or XVII and antibody of Group II or IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

Furthermore, searching the invention of Group I or XVII with either Group II or Group IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody to which the polypeptide binds require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not

required to identify the antibodies of Group II or IV. In addition, the technical literature search for the polypeptide of Groups I and XVII and the antibody of Group II or IV is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

Invention pairs II and III, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibodies can be administered to a patient for treatment of disease. Furthermore search and consideration of the methods requires search for each of the different steps in the methods, which is not required for search for the products.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions cannot be used together. Invention I is drawn to polypeptides, whereas Invention III is drawn to methods of detecting polypeptides. The latter requires antibodies, and the former does not encompass antibodies. Thus the two groups are patentably distinct. Furthermore search for the products of Group I would not be informative as to the novelty of the methods of Group III, so consideration of both groups together would be burdensome for the examiner.

Invention pairs II and IV, III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to patentably distinct products and methods of using those distinct products. Invention II is drawn to an antibody which binds to chicken II GnRH, whereas Invention IV is drawn to an antibody which binds to a receptor. These cannot be substituted one for the other, as the epitopes in the receptor are different from those in the very small ligand. Additionally, search for one of the antibodies would not be informative as to the novelty of the other. Similarly, methods of using the two different antibodies are patentably distinct.

Inventions I – V are not related to either of Inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the

instant case, the different inventions of groups VI and VII require nucleic acids, which are not required for any of inventions I – V. Furthermore search for the methods of Groups VI – VII require search for the starting materials and method steps of those groups, which are not required for the searches of Groups I – V. Thus consideration of either of Groups VI or VII with any of Groups I – V would be burdensome for the examiner.

Inventions I – III are not related to Invention V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions the inventions of Groups I and II are drawn to GnRH analogs and antibodies, whereas Group V requires antibodies that bind to GnRH receptors. As these antibodies are not encompassed in either of Groups I or II, the methods of using them are patentably distinct. Furthermore search for Group V requires search for the starting materials and steps, which are not encompassed within Groups I and II or Group III, a method of using the antibody of Group II. Thus consideration of Group V with either Group I or II would be burdensome.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions cannot be used together. The antibodies of Group IV cannot be used in the methods of Group III. Search for the antibodies of Group IV is not coextensive with methods of detecting a protein to which it does not bind, so consideration of both groups together would be burdensome.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are both methods of detecting nucleic acids, but they require different starting materials which cannot be substituted one for the other. Since different starting materials are required, the searches for the two groups are divergent and consideration of both together would be burdensome for the examiner.

Inventions I – VII, XII, and XVII – XX are all unrelated to Inventions VIII – XI and XIII – XVI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and

§ 806.06). In the instant case, the inventions of Groups VIII – XI and XIII – XVI each require introducing nucleic acids into cells. This step is not required for any of the other methods, and cannot be performed with any of the products, either antibodies or proteins. Thus these methods are independent and distinct from the methods and products of Groups I – VII, XII, and XVII – XX. As search for methods of introducing nucleic acids into cells would not be informative as to the novelty or non-obviousness of any other claimed product or method, consideration of any of groups I – VII, XII, or XVII – XX with any of groups VIII – XI or XIII – XVI would be burdensome for the examiner.

Inventions VIII – XI and XIII – XVI are unrelated, each to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions all are drawn to methods comprising administering nucleic acids to cells. However, each Group as set forth above requires administration of a patentably distinct oligonucleotide. These cannot be substituted one for the other. For example, an oligonucleotide comprising at least 10 consecutive nucleic acids complementary to SEQ ID NO:1 cannot be substituted for an oligonucleotide comprising at least 10 consecutive nucleic acids which encode a receptor for SEQ ID NO:6. Furthermore search for each group requires a separate search of the sequence databases, so consideration of more than one of these groups together would be burdensome for the examiner.

Invention XII is not related to any of Inventions I – VII, XVII, or XIX – XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XII is drawn to introducing the protein SEQ ID NO:6 into a cell. This cannot be performed with any of the products of Groups I – II or IV and requires different starting materials and methods steps from the methods of Groups III, V – VII, XVII, and XIX – XX. Note that Group XVII requires the additional step of triggering a biological mechanism, which is not required for Group XII, and Group XIX requires that the polypeptide be administered to a patient or animal, whereas group XII requires that it be introduced into a cell. As divergent searches are required, consideration of Group XII with any of Groups I – VII, XVII, or XIX – XX would be burdensome for the examiner.

Invention XVIII is related to Inventions XII, XVII, and XIX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide product (Group XVII) can be used in any of the three sets of methods. Furthermore search for the product will not be informative as to whether any of the methods are novel or non-obvious, as there may be new methods for old products. As divergent searches are required, consideration of Group XVIII with any of Groups XII, XVII, or XIX would be burdensome for the examiner.

Inventions I – VII are not related to any of Inventions XVII – XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of Groups I, II, and IV cannot be substituted for the product of Group XVIII or used in any of the methods of Groups XVII or XIX – XX. Furthermore the methods of Groups III and V – VII each require starting materials and methods steps which are not required in the methods of Groups XVII – XX. As the searches required are divergent, consideration of any of Groups I – VII with any of Groups XVII – XX would be burdensome for the examiner.

Inventions XVII is not related to either of Inventions XIX or XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions require different starting materials and steps. The invention of Group XVII requires the step of triggering a biological mechanism within a cell, which is not required for either of Groups XIX or XX. Furthermore, Group XX requires administration of a receptor for SEQ ID NO:6, which is not required for Group XVII. As divergent searches are required, consideration of either Group XIX or XX with Group XVII would be burdensome.

Inventions XVIII – XIX are not related to Invention XX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, Group XX requires administration of a receptor for SEQ ID NO:6, which cannot be accomplished with the product of Group XVIII and cannot be substituted for the method of Group XIX. As Group XX requires search of the receptor, which is not required for consideration of either Group XVIII or XIX, consideration of either Group XVIII or XIX along with Group XX would be burdensome for the examiner.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search and encompass art-recognized divergent subject matter (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel E. Kolker, Ph.D.
July 6, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER

Application No.: 10/820477

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Claim 1 contains a sequence not identified by SEQ ID NO!

Applicant Must Provide:

ONLY if the sequence in claim 1 is not in the current Sequence Listing

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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